

REMARKS

This Preliminary Amendment is being filed along with an RCE application. By this Preliminary Amendment, claims 13-16 have been added. Accordingly, claims 1 and 9-16 are pending in this application. Consideration of this application is respectfully requested.

Turning to the outstanding rejection, claims 1 and 9-12 were rejected under 35 USC §103(a) as being unpatentable over US Patent No. 3,842,996 (hereafter "Carlisle"). Applicants respectfully traverse this rejection.

The present invention is concerned with a method of treating an acute wound using a wound dressing (as a substitute for a biological dressing or skin graft) wherein the wound dressing comprises highly absorbent fibers.

Applicants have found that by the use of absorbent fibers in the above method, fibrous dressings can be used as substitutes for biological dressings. Biological dressings are sophisticated and therefore tend to be expensive and carry the same risks of cross-contamination that are encountered with blood and blood products. The advantages of the new method embodied in applicants' claims include that the dressings can be used as a substitute for a biological dressing at lower cost and without the risk of contamination.

Carlisle, on the other hand, is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting (col. 6 line 36 to 37). Carlisle does not, therefore, consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle would not, therefore, motivate the person of ordinary skill to use a fibrous dressing as a substitute for a biological dressing.

Further, applicants' dressings have been observed to promote the migration of enzymes, neutrophils, fibroblasts and cellular debris into the dressing, and this "vertical wicking" (that is in a direction perpendicular to the plane of the dressing) is thought to modulate the inflammatory response of the wound and contribute to healing. (See applicant's description at page 3, third paragraph, and Example 2.)

Carlisle by contrast emphasizes the high density of his dressing which is said to bar the passage of particles of greater than 25 microns through the fibrous structure. (See column 3, lines 17 to 53). The exudate is spread laterally rather than vertically. The lateral spread enables the dressing to be delaminated and changed while on the wound. The supposed vertical wicking of Carlisle referred to by the Examiner in the final rejection is not vertical wicking in the sense of being perpendicular to the plane of the dressing. Rather, the wicking is lateral, in the plane of the dressing. The test at column 4 refers to strips of the dressing hung vertically

with one end dipped in liquid. This wicking direction is vertical in the test but lateral in relation to the dressing and the wound.

The overall teaching of Carlisle is to make a dense laminar dressing that wicks laterally and bars the movement of exudate perpendicular to the plane of the dressing. Carlisle, therefore, teaches away from Applicants' method wherein the dressing promotes vertical wicking and allows wound fluid to penetrate the whole dressing. (See example 2.) This is contrary to the position taken by the Examiner, in the Advisory Action, that applicants have not demonstrated any unexpected or superior results attributable to vertical wicking.

Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds as claimed, the dressing adheres to the wound. (See page 5, second paragraph). This type of behavior would usually only be seen with a biological dressing such as allograft and is a truly surprising discovery by the Applicants hereof. It is illustrated particularly in Example 1, page 6, where it is described that the wound dressing dried out to form a crust as wound healing was in progress, and remained in place for 14 days. This method of use is very different from that contemplated in Carlisle where the emphasis is on the dressing being changed. Carlisle teaches that the dressing requires changing particularly by delaminating the dressing (column 3, lines 43 to 45) and applying a new dressing. This teaches away from a dressing that becomes adhered to the wound and is left in place. According to the Advisory Action, the claims are relative with regard to the amount of time the wound dressing needs to adhere to the wound. Applicants disagree. The claims require that the dressing adhere for a period of time effective to promote epithelial outgrowth and vertical wicking (claims 1, 15 and those claims dependent thereon); or that the dressing be left in place until it dries out to form a crust (new claims 13 and 14). Again, this method of use is very different from that contemplated in Carlisle where the emphasis is on the dressing being changed.


Still a further important difference is that, to remove the dressing of Carlisle, we are told that the dressing must be saturated or be provided with a wound contact layer, e.g., a plastic material (column 6, lines 1 to 11). Applicants found no difficulty in removing the dressing as described. (See the examples).

For all these reasons, applicants consider that Carlisle does not disclose or make obvious the methods claimed in this application.

Accordingly, in view of the foregoing, favorable consideration of this application, and allowance of the pending claims, are all earnestly solicited.

Respectfully submitted,

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Date: April 11, 2006